

## ACCREDITATION OF METHADONE MAINTENANCE TREATMENT: ASSURING QUALITY OF CARE

### *History and Effectiveness of Methadone Maintenance Treatment*

The Department of Health and Human Services (HHS), the Department of Justice (DOJ), and the White House Office of National Drug Control Policy have agreed to new proposed regulations to improve the quality and oversight of substance abuse treatment programs that use methadone and other medication to treat heroin and similar addictions. Under the proposed rule, federal oversight of narcotic treatment programs would be shifted from direct inspection by the Food and Drug Administration (FDA) to a system administered by the Substance Abuse and Mental Health Services Administrations' (SAMHSA) Center for Substance Abuse Treatment (CSAT). The proposal, which was published in the Federal Register, relies on accreditation by independent organizations and states, in accordance with standards established by CSAT. These standards emphasize improving the quality of care, such as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This new program relies on best practice guidelines CSAT has developed over the last 10 years.

Methadone hydrochloride, or methadone as it is commonly known, is a synthetic opiate compound (an opioid) originally synthesized for use as an analgesic in World War II. Between 1958 and 1962, it was introduced at the U.S. Public Health Service Hospital in Lexington, Kentucky; Beth Israel Medical Center in New York City; and a few other limited sites for use in "detoxifying" people who had become addicted to heroin. Unfortunately, once they had been medically withdrawn, most of these people returned to heroin use within days or weeks.

In the 1960s, Drs. Vincent Dole and Marie Nyswander demonstrated that a single daily dose of methadone could suppress heroin withdrawal symptoms for 24 hours. They went on to demonstrate that methadone, given daily, would continue to prevent withdrawal symptoms, craving, and drug-seeking behavior. Furthermore, because methadone blocks the effect of any superimposed short-acting opiate drug, it is extremely difficult for former heroin addicts who have been stabilized on methadone to "override" daily doses of 60 milligrams with heroin and to feel any euphoria or other perceived or observable effects (100 mg.  $\pm$  20 mg. doses of methadone are considered optimum for most patients).

Approved by the Food and Drug Administration (FDA) in 1972 for use in treating opiate addiction, methadone quickly became the primary means of treating this type of addiction. Today, an estimated 138,000 to 170,000 individuals in the United States receive methadone daily and thousands more have benefitted from it throughout the years. (In addition, approximately 2500 individuals receive levo-alpha-acetyl-methadol, or LAAM, which was approved by the FDA in 1993 for use in the treatment of opiate/opioid addiction.)

Methadone's effectiveness, and the absence of *any* serious, long-term side effects from using it, have been demonstrated in numerous studies conducted over the past 30 years. Among the most commonly cited outcomes are the following:

- ! **Consumption of all illicit drugs declines** to less than 40 percent of pretreatment levels during the first year and eventually reaches 15 percent of pre-treatment levels for patients who remain in treatment 2 years or more (Ball and Ross, 1991; Hubbard, Marsden, et al., 1986).
- ! **Crime is reduced substantially:** For example, in the most detailed study of treatment outcomes to date, Ball and Ross (1991) showed that during the first 4 months of treatment, crime decreased from 237 crime days per year per 100 addicted persons during an average

year of their addiction to 69 crime days per year per 100 patients, a reduction of more than 70 percent (p. 205), declining further to only 14.5 crime days per year for patients in treatment 6 years or more.

- ! **Fewer individuals become infected with HIV:** For example, a study by Metzger, et al. (1993) showed that over a 3-year period, 5 percent of patients in methadone treatment became HIV positive (over and above those already positive at admission), while among a cohort of out-of-treatment addicts in the same neighborhood, 26 percent became HIV positive (over and above those already positive at baseline).
  
- ! **Individual functioning improves, as evidenced in improved family and other social relationships, increased employment, improved parenting,** and so forth (CSAT, 1994; Lowinson, et al, 1992). For example, a study of the first 15 years of methadone treatment documented employment rates of patients that were just below 60 percent; even in the 1980s, when the economy weakened, crack use increased, and HIV infection rates increased dramatically, social productivity levels and employment remained at about 40 percent (Lowinson, et al, 1992).

Methadone has been shown to be safe; it produces no serious or long-term side effects, and may improve immune system functioning in people who have experienced the deleterious effects of heroin addiction. Methadone's clinical effectiveness has been documented in more than 300 published research studies (Hubbard, Marsden, et al., 1986; Sells, Demaree, et al., 1979). Furthermore, "comprehensive methadone maintenance, when combined with appropriate prenatal care, can reduce the incidence of obstetrical and fetal complications ... and there is no reported evidence of any toxic effects of methadone in the woman, fetus, or child" (Institute of Medicine, 1995, p. 8). Finally, at an annual average cost of \$4,319/patient, methadone maintenance treatment is cost effective. In fact, a comprehensive examination of economic benefits and costs performed on the Treatment Outcome Prospective Study (TOPS) (Harwood, et al, 1988) yielded a final cost/benefit ratio of 1:4, based on examination of the average cost of treatment, detailed data on rates of criminal activities, and costs to society of various crimes.

#### *Regulation of Methadone Maintenance Treatment*

Despite its documented effectiveness, methadone's use in treating addiction has been subject to extensive levels of Federal, State, and local regulation. FDA, the Drug Enforcement Administration (DEA), States, and even some counties have promulgated regulations governing methadone treatment. Even though this medical intervention is subject to an extraordinary degree of regulation, methadone treatment programs continue to provide effective treatment for thousands of individuals. As Mary Jeanne Kreek, one of the premier addiction researchers in the field has argued: "The greatest needs with respect to methadone maintenance treatment now begin with the need to change general public attitudes and therefore the attitudes of policymakers with respect to this treatment modality" (CSAT, 1993, p. 140).

#### *Reforming Methadone Treatment*

Reforming the current methadone regulatory system has been on the agenda for more than a decade with recommendations for change coming from providers, researchers, blue-ribbon committees, and field studies of methadone treatment programs. Reports by the General Accounting Office (GAO), the Institute of Medicine (IOM), and an NIH Consensus Development Panel (1997) have all reflected similar conclusions:

- The system for monitoring compliance with the current Federal regulations is inefficient and poorly implemented.
- The Federal methadone regulations unnecessarily restrict the practice of medicine, discourage clinical judgment, and fail to focus on outcomes.
- Wide variability exists in quality and comprehensiveness of treatment for opioid addiction; clinical practice guidelines should supplement but not replace regulations, and should provide a vehicle by which patient care may be improved.

Under a proposed new federal rule, FDA responsibilities may be shifted to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Center for Substance Abuse Treatment (CSAT). The new system would require opioid treatment programs to be accredited by CSAT-approved accreditation bodies. This approach relies on best practice guidelines and parallels the accreditation requirements that apply to the mainstream health and behavioral health care systems.

#### *Potential Impact of Accreditation on Methadone Maintenance Treatment*

Basically, a monitoring system based on accreditation is expected to have the following results:

- Improve quality of care and reduce variability in the standard of care provided.
- Increase professional discretion in providing medical care and individualized treatment plans.
- Position methadone maintenance treatment more closely within mainstream health care, thereby potentially expanding the availability of treatment within hospitals and health maintenance organizations, both of which are accustomed to meeting accreditation standards.
- Help to reduce the stigma often associated with opioid treatment.
- Increase focus on performance outcomes.

#### *Accreditation of Opioid Treatment Programs: CSAT's Approach*

In 1998, CSAT implemented a study to examine the impact and costs of accreditation for the methadone treatment system. Approximately 175 randomly selected methadone treatment programs are participating, one-fourth of which have been designated as control sites. The accreditation system is expected to be fully operational by 2001, and data from the study will be used to inform and fine-tune the new accreditation system.

Two nationally-recognized accrediting organizations—CARF...The Rehabilitation Accreditation Commission and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)—survey and determine the accreditation status of programs participating in the pilot study. Both organizations have developed methadone-specific standards, based on CSAT's guidelines for opioid treatment programs. These standards, in turn, have been incorporated into each organization's behavioral health care standards. Thus, to be accredited, a program must meet those standards that apply to all behavioral health care programs accredited by the organization *as well as* the methadone treatment-specific standards.

All programs participating in the study receive training on CARF and JCAHO standards and are eligible for technical assistance that is being provided to help programs fully prepare for their onsite surveys. CARF and JCAHO will make accreditation decisions granting or denying accreditation. Surveys of the programs began in October 1999 and are expected to continue through December 2000.

Data collected from pre- and post-accreditation site visits, survey findings, and information provided by programs and others during the study will be analyzed to assess the process, impacts, and costs of accreditation. The results will be used by CSAT and other involved Federal agencies to help make system-wide accreditation as effective as possible.

*How can the proposed new system of accreditation of methadone treatment programs benefit the managed care industry?*

The proposed accreditation system offers several potential benefits for purchasers and payers of addiction treatment services:

- Improved and consistent operational processes and clinical practices that meet the requirements of two nationally-recognized accrediting bodies.
- Improved Federal oversight through regularly required accreditation surveys focusing on the quality and outcome of care, in contrast to irregular onsite inspections for compliance with regulations.
- Increased likelihood of individualized treatment provided by clinicians who will be able to exercise medical judgment in managing methadone/LAAM doses, tailoring services to patients' periodically-assessed needs and stage of treatment, specifying a schedule of drug tests/screens, approving and monitoring take-home (unsupervised) doses, and communicating closely with a patient to determine whether, when, and how medically supervised withdrawal from medication might be undertaken.
- Treatment based on current best practices as evidenced by research findings and/or the consensus of experts in the addictions field, and updated as new knowledge becomes available.
- Improved consistency in the quality of comprehensive assessment and treatment services, with an increased focus on the effectiveness of treatment and on patient outcomes. Treatment programs will be expected to measure and review indicators of program performance, such as patient outcomes, improved functional status, reductions in use of costly health care services, among others.

## References

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